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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/555,383

11/03/2005

Kazuhiro Ban

03500.102556

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03/27/2008

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EXAMINER

SAJJADI, FEREDYDOUN GHOTB

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

03/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/555,383	Applicant(s) BAN ET AL.	
	Examiner FEREYDOUN G. SAJJADI	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-14 are pending in the Application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

1. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, drawn to a kit for immobilizing an organic substance on a substrate, comprising a substrate having a surface at least part of which contains aluminum oxide; and a binding domain for immobilizing the organic substance on the substrate, having an ability to bind to the aluminum oxide and being coupled with the organic substance, wherein: the binding domain contains at least a peptide composed of one or more amino acids; and a structure comprising the same.

Group II, claim(s) 9 and 10 drawn to a method of manufacturing a structure having an organic substance immobilized on a substrate, comprising the steps of: preparing an organic substance - binding domain fused product composed of the substrate having a surface at least part of which contains aluminum oxide and a binding domain having an ability to bind to the aluminum oxide and coupled with the organic substance; and immobilizing the organic substance on the substrate by bringing the fused product into contact with the surface of the substrate to cause a peptide having an ability to bind to the aluminum oxide to specifically bind to the aluminum oxide.

Group III, claim(s) 11 and 14, drawn to a peptide of SEQ ID NOS: 1-32; and an organic substance binding domain fused product comprising the peptide of SEQ ID NOS: 1-32, having an affinity to aluminum oxide.

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Group IV, claim(s) 12 and 13, drawn to a DNA molecule encoding a peptide chain having an amino acid sequence of SEQ ID NOS: 1-32; and an expression vector which has an ability to express a binding domain peptide of SEQ ID NOS: 1-32, having an affinity to aluminum oxide.

Please note that PCT Rule 13.2, no longer specifies the combinations of categories of invention which are considered to have unity of invention. The categories of invention in former PCT Rule 13.2 have been replaced with a statement describing the method for determining whether the requirement of unity of invention is satisfied. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term “special technical features” is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

2. Groups I, III and IV claims encompass a plurality of distinct inventions exemplified by structurally distinct peptides and their various modifications, and nucleic acids encoding the same, that comprise distinct nucleic acid and polypeptide sequences. These are exemplified by SEQ ID NOS: 1-32. Because the peptides and nucleic acids have distinct structural sequences, not commonly shared, they lack unity of invention. Applicant is required to choose a single, specific SEQ ID NO as a peptide, or a nucleic acid encoding the peptide, should any of the inventions of Groups I, III or IV be elected for examination. This is not a species restriction requirement.

Applicants should note that while MPEP 803.04 allows for the examination of up to ten sequences in a single examination without restriction, the waiver for up to 10 nucleotide sequences is permissive and not a requirement. The waiver went into effect in 1996, well before the exponential growth of the nucleic acid and protein databases. Since the addition of these guidelines to the MPEP the biological sequence databases required to be searched for the examination of any biological sequence have grown tremendously (e.g. a 54-fold increase in the number of nucleic acid sequences in the GenBank data base and a 91-fold increase in the number of nucleotides between 1996 and February 2006), and thus the Technology Center no

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longer routinely examines and searches more than one independent biological sequence for any single application (a pre-OG notice

<<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/sequence02212007.pdf>>). The

present restriction requirement conforms with this policy as it has required that the application be restricted to one nucleotide polypeptide sequence.

37 CFR 1.475 (e) states:

“The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.”

In view of 37 CFR 1.475 (e), Groups I and II are considered a plurality of the inventions listed in claims 4, and 11-14.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The technical feature, which is shared by Groups I-IV, is a substrate containing aluminum oxide to which peptides having a binding domain for said substrate can bind.

Groups I-IV do not share a special technical feature over the art because the inventions lack an inventive step under PCT Article 33(3) as being obvious over Coletti-Previero et al. (Anal. Biochem. 180:1-10; 1989), who describe substrates containing a chemically activated alumina-phosphonate group onto which enzymes or other molecules can be immobilized (Abstract).

The claims in Groups I-IV are drawn to a distinct products (i.e. immobilizing substrate, peptides and nucleic acid), and a distinct method employing distinct steps, requiring non-coextensive search and examination. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

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The inventions of Groups I and II constitute products and related process. MPEP 1893.03(d) states: If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/

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Fereydoun G. Sajjadi, Ph.D.

Examiner, Art Unit 1633